



BIOLASE Technology, Inc.  
4 Cromwell  
Irvine, CA 92618

K130465

## 510(k) Summary

APR 11 2013

### Submitter:

Biolase Technology, Inc.  
4 Cromwell  
Irvine, California 92618  
(949) 226-8470 - Phone  
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Colleen Boswell - Contact Person

Date Summary Prepared: February 2013

- Trade Name - *Epic 10S*
- Common Name - Diode Laser
- Classification Name - Laser surgical instrument for use in general and plastic surgery and in dermatology, per 21 CFR 878.4810
- Product Code - GEX

### Device for Which Substantial Equivalence is Claimed:

- *Diolase 10S*, Biolase Technology, Inc., K121327

### Device Description

The *EPIC 10S* system uses an Indium Gallium Arsenide Phosphorous (InGaAsP) solid state laser diode to emit infrared laser energy which is transmitted via a flexible fiber optic cable to a handpiece that emits the energy to the target site. A visible light is emitted at the same time to visually identify the treatment location. The *EPIC 10S* laser is comprised of a base console, a detachable delivery system, tips, and a wireless footswitch. Various types of the single use tips are included for different applications and the device is activated by means of a wireless footswitch. The *Epic 10S* delivery system consists of the following: Fiber Optic Assembly, Surgical Handpiece, and Single-use tips.

### Statement of Intended Use

The *Epic 10S* is intended for use as a laser surgical instrument in general and plastic surgery and in dermatology. It is indicated for the following expanded Indications for Use:

#### ***Ear, Nose and Throat and Oral Surgery:***

Hemostasis, incision, excision, ablation, and vaporization of tissues from the ear, nose, throat and adjacent areas, including soft tissue in the oral cavity, such as:

- Removal of benign lesions from ear, nose and throat
- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in-situ
- Ablation and vaporization of hyperkeratosis
- Laryngeal papillectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

**Arthroscopy:**

Hemostasis, incision, excision, vaporization, and ablation of joint tissues during arthroscopic surgery, such as:

- Meniscectomy
- Synovectomy
- Chondromalacia

**Gastroenterology:**

Hemostasis, incision, excision, and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy, such as:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps
- Hemostasis of colonoscopy
- Hemostasis of esophageal varices

**Orthopedics:**

- Dissect and coagulate

**General Surgery, Dermatology & Plastic Surgery, and Podiatry:**

Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of Keloids
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcer
- Hepatobiliary
- Mastectomy
- Dermabrasion
- Vaporization & hemostasis of capillary hemangioma
- Excision, vaporization & hemostasis of abdominal tumors
- Excision, vaporization & hemostasis of rectal pathology

- Pilonidal cystectomy
- Herniorrhaphy
- Adhesiolysis
- Parathyroidectomy
- Laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs

**GI/GU:**

Excision, vaporization, and hemostasis of abdominal and rectal tissues, such as:

- Hemorrhoidectomy
- Excision, vaporization, and hemostasis of rectal pathology
- Excision, vaporization, and hemostasis of abdominal tumors

**Gynecology:**

Ablation, excision, hemostasis, and vaporization of tissue, such as:

- Excision or vaporization of condylomata acuminata
- Vaporization of CIN (cervical intraepithelial neoplasia)
- Cervical conization
- Menorrhagia
- Ovarian cystectomy

**Neurosurgery:**

Vaporization, coagulation, excision, incision, ablation and hemostasis of tissue, such as:

- Hemostasis in conjunction with meningiomas
- Percutaneous Disc Decompression (PLDD)

**Ophthalmology:**

- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor Excision
- Blepharoplasty

**Pulmonary Surgery:**

Hemostasis, vaporization, and excision of tissue, such as:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction

**Cardiac Surgery:**

- Coagulation and hemostasis of cardiac tissue

**Thoracic Surgery:**

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

***Urology:***

Hemostasis, vaporization, incision, coagulation, ablation, and excision of tissues, such as:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- Lesions of external genitalia
- Circumcision
- Vaporization of the prostate to treat benign prostate hyperplasia (BPH)

***Dermatology/Aesthetics:***

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, venulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines, epidermal nevi, spider nevi.
- Dermatological surgery: Condyloma acuminata, warts, small non-malignant skin tumors, small semi-malignant tumors as basalomas, Bowe and Kaposi sarcoma, warty leucoplasty and ulcers debridement.
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment

***Vascular Surgery:***

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinulectasia of the legs and face
- Treatment of reticular veins and branch varicosities

**Summary of Technological Characteristics**

<b>Descriptive Information</b>	<b><i>Epic 10S</i></b>	<b>Diolase 10S (K121327)</b>
Company	<b>Biolase Technology, Inc.</b>	Biolase Technology, Inc.

Descriptive Information	<i>Epic 10S</i>	<i>Diolase 10S (K121327)</i>
Indications for Use	<p>The <i>Epic 10S</i> is intended for use as a laser surgical instrument in general and plastic surgery and in dermatology. It is indicated for the following expanded Indications for Use:</p> <p><b><i>Ear, Nose and Throat and Oral Surgery:</i></b> Hemostasis, incision, excision, ablation, and vaporization of tissues from the ear, nose, throat and adjacent areas, including soft tissue in the oral cavity, such as:</p> <ul style="list-style-type: none"> <li>• Removal of benign lesions from ear, nose and throat</li> <li>• Excision and vaporization of vocal cord nodules and polyps</li> <li>• Incision and excision of carcinoma in-situ</li> <li>• Ablation and vaporization of hyperkeratosis</li> <li>• Laryngeal papillectomy</li> <li>• Excision and vaporization of herpes simplex I and II</li> <li>• Neck dissection</li> </ul> <p><b><i>Arthroscopy:</i></b> Hemostasis, incision, excision, vaporization, and ablation of joint tissues during arthroscopic surgery, such as:</p> <ul style="list-style-type: none"> <li>• Meniscectomy</li> <li>• Syovectomy</li> <li>• Chondromalacia</li> </ul> <p><b><i>Gastroenterology:</i></b> Hemostasis, incision, excision, and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy, such as:</p> <ul style="list-style-type: none"> <li>• Hemostasis of upper and lower GI bleeding</li> <li>• Excision and vaporization of colorectal carcinoma</li> <li>• Excision of polyps</li> <li>• Hemostasis of colonoscopy</li> <li>• Hemostasis of esophageal varices</li> </ul> <p><b><i>Orthopedics:</i></b></p> <ul style="list-style-type: none"> <li>• Dissect and coagulate</li> </ul> <p><b><i>General Surgery, Dermatology &amp; Plastic Surgery, and Podiatry:</i></b> Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis,</p>	<p>The <i>Diolase 10S</i> is intended for use as a laser surgical instrument in general and plastic surgery and in dermatology. It is indicated for the following expanded Indications for Use:</p> <p><b><i>Ear, Nose and Throat and Oral Surgery:</i></b> Hemostasis, incision, excision, ablation, and vaporization of tissues from the ear, nose, throat and adjacent areas, including soft tissue in the oral cavity, such as:</p> <ul style="list-style-type: none"> <li>• Removal of benign lesions from ear, nose and throat</li> <li>• Excision and vaporization of vocal cord nodules and polyps</li> <li>• Incision and excision of carcinoma in-situ</li> <li>• Ablation and vaporization of hyperkeratosis</li> <li>• Laryngeal papillectomy</li> <li>• Excision and vaporization of herpes simplex I and II</li> <li>• Neck dissection</li> </ul> <p><b><i>Arthroscopy:</i></b> Hemostasis, incision, excision, vaporization, and ablation of joint tissues during arthroscopic surgery, such as:</p> <ul style="list-style-type: none"> <li>• Meniscectomy</li> <li>• Syovectomy</li> <li>• Chondromalacia</li> </ul> <p><b><i>Gastroenterology:</i></b> Hemostasis, incision, excision, and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy, such as:</p> <ul style="list-style-type: none"> <li>• Hemostasis of upper and lower GI bleeding</li> <li>• Excision and vaporization of colorectal carcinoma</li> <li>• Excision of polyps</li> <li>• Hemostasis of colonoscopy</li> <li>• Hemostasis of esophageal varices</li> </ul> <p><b><i>Orthopedics:</i></b></p> <ul style="list-style-type: none"> <li>• Dissect and coagulate</li> </ul> <p><b><i>General Surgery, Dermatology &amp; Plastic Surgery, and Podiatry:</i></b> Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis,</p>

Descriptive Information	Epic 10S	Diolase 10S (K121327)
	<p>incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:</p> <ul style="list-style-type: none"> <li>• Matrixectomy</li> <li>• Excision of neuromas</li> <li>• Excision of periungual and subungual warts</li> <li>• Excision of plantar warts</li> <li>• Excision of Keloids</li> <li>• Excision of cutaneous lesions</li> <li>• Hemorrhoidectomy</li> <li>• Appendectomy</li> <li>• Debridement of decubitus ulcer</li> <li>• Hepatobiliary</li> <li>• Mastectomy</li> <li>• Dermabrasion</li> <li>• Vaporization &amp; hemostasis of capillary hemangioma</li> <li>• Excision, vaporization &amp; hemostasis of abdominal tumors</li> <li>• Excision, vaporization &amp; hemostasis of rectal pathology</li> <li>• Pilonidal cystectomy</li> <li>• Herniorraphy</li> <li>• Adhesiolysis</li> <li>• Parathyroidectomy</li> <li>• Laparoscopic cholecystectomy</li> <li>• Thyroidectomy</li> <li>• Resection of organs</li> </ul> <p><b>GI/GU:</b> Excision, vaporization, and hemostasis of abdominal and rectal tissues, such as:</p> <ul style="list-style-type: none"> <li>• Hemorrhoidectomy</li> <li>• Excision, vaporization, and hemostasis of rectal pathology</li> <li>• Excision, vaporization, and hemostasis of abdominal tumors</li> </ul> <p><b>Gynecology:</b> Ablation, excision, hemostasis, and vaporization of tissue, such as:</p> <ul style="list-style-type: none"> <li>• Excision or vaporization of condylomata acuminata</li> <li>• Vaporization of CIN (cervical intraepithelial neoplasia)</li> </ul>	<p>incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:</p> <ul style="list-style-type: none"> <li>• Matrixectomy</li> <li>• Excision of neuromas</li> <li>• Excision of periungual and subungual warts</li> <li>• Excision of plantar warts</li> <li>• Excision of Keloids</li> <li>• Excision of cutaneous lesions</li> <li>• Hemorrhoidectomy</li> <li>• Appendectomy</li> <li>• Debridement of decubitus ulcer</li> <li>• Hepatobiliary</li> <li>• Mastectomy</li> <li>• Dermabrasion</li> <li>• Vaporization &amp; hemostasis of capillary hemangioma</li> <li>• Excision, vaporization &amp; hemostasis of abdominal tumors</li> <li>• Excision, vaporization &amp; hemostasis of rectal pathology</li> <li>• Pilonidal cystectomy</li> <li>• Herniorraphy</li> <li>• Adhesiolysis</li> <li>• Parathyroidectomy</li> <li>• Laparoscopic cholecystectomy</li> <li>• Thyroidectomy</li> <li>• Resection of organs</li> </ul> <p><b>GI/GU:</b> Excision, vaporization, and hemostasis of abdominal and rectal tissues, such as:</p> <ul style="list-style-type: none"> <li>• Hemorrhoidectomy</li> <li>• Excision, vaporization, and hemostasis of rectal pathology</li> <li>• Excision, vaporization, and hemostasis of abdominal tumors</li> </ul> <p><b>Gynecology:</b> Ablation, excision, hemostasis, and vaporization of tissue, such as:</p> <ul style="list-style-type: none"> <li>• Excision or vaporization of condylomata acuminata</li> <li>• Vaporization of CIN (cervical intraepithelial neoplasia)</li> </ul>

Descriptive Information	Epic 10S	Diolase 10S (K121327)
	<ul style="list-style-type: none"> <li>• Cervical conization</li> <li>• Menorrhagia</li> <li>• Ovarian cystectomy</li> </ul> <p><b>Neurosurgery:</b> Vaporization, coagulation, excision, incision, ablation and hemostasis of tissue, such as:</p> <ul style="list-style-type: none"> <li>• Hemostasis in conjunction with meningiomas</li> <li>• Percutaneous Disc Decompression (PLDD)</li> </ul> <p><b>Ophthalmology:</b></p> <ul style="list-style-type: none"> <li>• Dacryocystorhinostomy transcanalicular</li> <li>• Open DCR</li> <li>• Tumor Excision</li> <li>• Blepharoplasty</li> </ul> <p><b>Pulmonary Surgery:</b> Hemostasis, vaporization, and excision of tissue, such as:</p> <ul style="list-style-type: none"> <li>• Tracheobronchial malignancy or stricture</li> <li>• Benign and malignant pulmonary obstruction</li> </ul> <p><b>Cardiac Surgery:</b></p> <ul style="list-style-type: none"> <li>• Coagulation and hemostasis of cardiac tissue</li> </ul> <p><b>Thoracic Surgery:</b></p> <ul style="list-style-type: none"> <li>• Thoracotomy</li> <li>• Pulmonary resection</li> <li>• Hemostasis</li> <li>• Pericardiectomy</li> <li>• Adhesiolysis</li> <li>• Coagulation of blebs and bullae</li> </ul> <p><b>Urology:</b> Hemostasis, vaporization, incision, coagulation, ablation, and excision of tissues, such as:</p> <ul style="list-style-type: none"> <li>• Vaporization of urethral tumors</li> <li>• Release of urethral stricture</li> <li>• Removal of bladder neck obstruction</li> <li>• Excision and vaporization of condyloma</li> <li>• Lesions of external genitalia</li> <li>• Circumcision</li> </ul>	<ul style="list-style-type: none"> <li>• Cervical conization</li> <li>• Menorrhagia</li> <li>• Ovarian cystectomy</li> </ul> <p><b>Neurosurgery:</b> Vaporization, coagulation, excision, incision, ablation and hemostasis of tissue, such as:</p> <ul style="list-style-type: none"> <li>• Hemostasis in conjunction with meningiomas</li> <li>• Percutaneous Disc Decompression (PLDD)</li> </ul> <p><b>Ophthalmology:</b></p> <ul style="list-style-type: none"> <li>• Dacryocystorhinostomy transcanalicular</li> <li>• Open DCR</li> <li>• Tumor Excision</li> <li>• Blepharoplasty</li> </ul> <p><b>Pulmonary Surgery:</b> Hemostasis, vaporization, and excision of tissue, such as:</p> <ul style="list-style-type: none"> <li>• Tracheobronchial malignancy or stricture</li> <li>• Benign and malignant pulmonary obstruction</li> </ul> <p><b>Cardiac Surgery:</b></p> <ul style="list-style-type: none"> <li>• Coagulation and hemostasis of cardiac tissue</li> </ul> <p><b>Thoracic Surgery:</b></p> <ul style="list-style-type: none"> <li>• Thoracotomy</li> <li>• Pulmonary resection</li> <li>• Hemostasis</li> <li>• Pericardiectomy</li> <li>• Adhesiolysis</li> <li>• Coagulation of blebs and bullae</li> </ul> <p><b>Urology:</b> Hemostasis, vaporization, incision, coagulation, ablation, and excision of tissues, such as:</p> <ul style="list-style-type: none"> <li>• Vaporization of urethral tumors</li> <li>• Release of urethral stricture</li> <li>• Removal of bladder neck obstruction</li> <li>• Excision and vaporization of condyloma</li> <li>• Lesions of external genitalia</li> <li>• Circumcision</li> </ul>

Descriptive Information	<i>Epic 10S</i>	<i>Diolase 10S (K121327)</i>
	<ul style="list-style-type: none"> <li>• Vaporization of the prostate to treat benign prostate hyperplasia (BPH)</li> </ul> <p><b>Dermatology/Aesthetics:</b></p> <ul style="list-style-type: none"> <li>• Photocoagulation of vascular &amp; dermatological lesions of the face and extremities</li> <li>• Photocoagulation of telangiectasia, venulectasia of the legs and face</li> <li>• Treatment of reticular veins and branch varicosities</li> <li>• Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas</li> <li>• Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines, epidermal nevi, spider nevi</li> <li>• Dermatological surgery: Condyloma acuminata, warts, small non-malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcoma and warty leucoplasty and ulcers debridement.</li> <li>• Seborrhic keratosis</li> <li>• Mixoid cyst</li> <li>• Papillary varix</li> <li>• Acne treatment</li> </ul> <p><b>Vascular Surgery:</b></p> <ul style="list-style-type: none"> <li>• Photocoagulation of vascular &amp; dermatological lesions of the face and extremities</li> <li>• Photocoagulation of telangiectasia, veinulectasia of the legs and face</li> <li>• Treatment of reticular veins and branch varicosities</li> </ul>	<ul style="list-style-type: none"> <li>• Vaporization of the prostate to treat benign prostate hyperplasia (BPH)</li> </ul> <p><b>Dermatology/Aesthetics:</b></p> <ul style="list-style-type: none"> <li>• Photocoagulation of vascular &amp; dermatological lesions of the face and extremities</li> <li>• Photocoagulation of telangiectasia, venulectasia of the legs and face</li> <li>• Treatment of reticular veins and branch varicosities</li> <li>• Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas</li> <li>• Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines, epidermal nevi, spider nevi</li> <li>• Dermatological surgery: Condyloma acuminata, warts, small non-malignant skin tumors, small semi-malignant tumors as basalomas, Bowe, Kaposi sarcoma and warty leucoplasty and ulcers debridement.</li> <li>• Seborrhic keratosis</li> <li>• Mixoid cyst</li> <li>• Papillary varix</li> <li>• Acne treatment</li> </ul> <p><b>Vascular Surgery:</b></p> <ul style="list-style-type: none"> <li>• Photocoagulation of vascular &amp; dermatological lesions of the face and extremities</li> <li>• Photocoagulation of telangiectasia, veinulectasia of the legs and face</li> <li>• Treatment of reticular veins and branch varicosities</li> </ul>
Laser Classification	IV (4)	IV (4)
Operating Voltage	100 – 240V ~ 1.5A	100V -240 ~ 2A
Laser Medium	InGaAsP	InGaAsP
Wavelength	940 ± 15nm	940 ± 15nm
Current Frequency	50 - 60 Hz	50 - 60 Hz



<b>Descriptive Information</b>	<b><i>Epic 10S</i></b>	<b><i>Diolase 10S (K121327)</i></b>
Max Output Power	10 watts	10 watts
Power Mode	Continuous, Pulse Modulation	Continuous, Pulse Modulation
Pulse Repetition Rate	Up to 50 KHz	Up to 10 KHz
Pulse Duration	0.01 ms – 10 Seconds	0.06 ms – 10 Seconds
Aiming Beam	Laser Diode, max 1mW, 625 - 670nm, Class 3B	Laser Diode, max 3mW, 630 – 670nm, Class 3B
Materials	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components	Medical grade plastics, steel, stainless steel, aluminum, brass, and electronic parts and components

#### Non-Clinical Test Data

Non-clinical testing was not performed on this device since the purpose of this 510(k) is to only expand the Indications for Use from the original 510(k) clearance under 510(k) No.: K121286. All indications included in this 510(k) have already been cleared by the FDA for an equivalent medical device manufactured by Biolase Technology, Inc.

#### Clinical Test Data

Clinical testing was not conducted on this device.

#### Conclusion

Based upon the comparison of the *Epic 10S* with the *Diolase 10S* previously cleared by the FDA, the clinical performance of the *Epic 10S* for the Indications for Use described above is deemed to be substantially equivalent to the legally-marketed predicate device, the *Diolase 10S*.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Center - WO66-G609  
Silver Spring, MD 20993-0002

Biolase Technology, Incorporated  
% Ms. Colleen Boswell  
Vice President, Regulatory Affairs  
4 Cromwell  
Irvine, California 92618-1816

April 11, 2013

Re: K130465

Trade/Device Name: Epic 10S

Regulation Number: 21 CFR 878.4810

Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology

Regulatory Class: Class II

Product Code: GEX

Dated: March 20, 2013

Received: March 21, 2013

Dear Ms. Boswell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/cdrh/mdr/> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours, FOR

**Peter DeRum -S**

Mark N. Melkerson  
Acting Director  
Division of Surgical Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

### Indications for Use

510(k) Number: K130465

Device Name: *Epic10S*

#### Indications for Use:

The *Epic 10S* is intended for use as a laser surgical instrument in general and plastic surgery and in dermatology. It is indicated for the following expanded Indications for Use:

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- Excision and vaporization of vocal cord nodules and polyps
- Incision and excision of carcinoma in-situ
- Ablation and vaporization of hyperkeratosis
- Laryngeal papillectomy
- Excision and vaporization of herpes simplex I and II
- Neck dissection

#### *Arthroscopy:*

Hemostasis, incision, excision, vaporization, and ablation of joint tissues during arthroscopic surgery, such as:

- Meniscectomy
- Synovectomy
- Chondromalacia

#### *Gastroenterology:*

Hemostasis, incision, excision, and vaporization of tissue in the upper and lower gastrointestinal tracts via endoscopy, such as:

- Hemostasis of upper and lower GI bleeding
- Excision and vaporization of colorectal carcinoma
- Excision of polyps
- Hemostasis of colonoscopy
- Hemostasis of esophageal varices

Prescription Use ☒ X

AND/OR

Over-The-Counter Use ☐

(Part 21CFR 801 Subpart D)

(21CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden  
2013.04.11 10:33:55 -04'00'

(Division Sign-Off) for MXM  
Division of Surgical Devices  
510(k) Number K130465

*Orthopedics:*

- Dissect and coagulate

*General Surgery, Dermatology & Plastic Surgery, and Podiatry:*

Excision, ablation, vaporization, and photocoagulation of skin lesions, hemostasis, incision, excision, vaporization, ablation, and debulking of soft tissue, abdominal, rectal, skin, fat or muscle tissue, and dermabrasion, such as:

- Matrixectomy
- Excision of neuromas
- Excision of periungual and subungual warts
- Excision of plantar warts
- Excision of Keloids
- Excision of cutaneous lesions
- Hemorrhoidectomy
- Appendectomy
- Debridement of decubitus ulcer
- Hepatobiliary
- Mastectomy
- Dermabrasion
- Vaporization & hemostasis of capillary hemangioma
- Excision, vaporization & hemostasis of abdominal tumors
- Excision, vaporization & hemostasis of rectal pathology
- Pilonidal cystectomy
- Herniorrhaphy
- Adhesiolysis
- Parathyroidectomy
- laparoscopic cholecystectomy
- Thyroidectomy
- Resection of organs

*GI/GU:*

Excision, vaporization, and hemostasis of abdominal and rectal tissues, such as:

- Hemorrhoidectomy
- Excision, vaporization, and hemostasis of rectal pathology
- Excision, vaporization, and hemostasis of abdominal tumors


Prescription Use   X    
(Part 21CFR 801 Subpart O)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21CFR 807 Subpart C)

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510(k) Number K130465

*Gynecology:*

Ablation, excision, hemostasis, and vaporization of tissue, such as:

- Excision or vaporization of condylomata acuminata
- Vaporization of CIN (cervical intraepithelial neoplasia)
- Cervical conization
- Menorrhagia
- Ovarian cystectomy

*Neurosurgery:*

Vaporization, coagulation, excision, incision, ablation and hemostasis of tissue, such as:

- Hemostasis in conjunction with meningiomas
- Percutaneous Disc Decompression (PLDD)

*Ophthalmology:*

- Dacryocystorhinostomy transcanalicular
- Open DCR
- Tumor Excision
- Blepharoplasty

*Pulmonary Surgery:*

Hemostasis, vaporization, and excision of tissue, such as:

- Tracheobronchial malignancy or stricture
- Benign and malignant pulmonary obstruction

*Cardiac Surgery:*

- Coagulation and hemostasis of cardiac tissue

*Thoracic Surgery:*

- Thoracotomy
- Pulmonary resection
- Hemostasis
- Pericardiectomy
- Adhesiolysis
- Coagulation of blebs and bullae

Prescription Use  X   
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*Urology:*

Hemostasis, vaporization, incision, coagulation, ablation, and excision of tissues, such as:

- Vaporization of urethral tumors
- Release of urethral stricture
- Removal of bladder neck obstruction
- Excision and vaporization of condyloma
- lesions of external genitalia
- Circumcision
- Vaporization of the prostate to treat benign prostate hyperplasia (BPH)

*Dermatology/Aesthetics:*

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, venulectasia of the legs and face
- Treatment of reticular veins and branch varicosities
- Pyrogenic granuloma, lymphangioma and lymphangiomatosis disease, angiofibromas
- Superficial benign vascular lesions including Telangiectasias, hemangioma, Port wine stains, angiokeratoma, and benign epidermal pigment lesions as lentigines, epidermal nevi, spider nevi
- Dermatological surgery: Condyloma acuminata, warts, small non-malignant skin tumors, small semi-malignant tumors as basalomas, Bowe and Kaposi sarcoma, warty leucoplasty and ulcers debridement
- Seborrheic keratosis
- Mixoid cyst
- Papillary varix
- Acne treatment

*Vascular Surgery:*

- Photocoagulation of vascular & dermatological lesions of the face and extremities
- Photocoagulation of telangiectasia, veinulectasia of the legs and face
- Treatment of reticular veins and branch varicosities

Prescription Use   X    
(Part 21CFR 801 Subpart D)

AND/OR

Over-The-Counter Use             
(21CFR 807 Subpart C)

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